K091634

Navilyst Medical

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# 510(k) Summary

MAR - 1 2010

## A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

## B. Contact

Lori Fitton
Regulatory Affairs Specialist
508-658-7938

or

Lorraine M. Hanley
Director, Global Regulatory Affairs
508-658-7945

## C. Device Name

| | |
|---|---|
| Trade name: | Flush Connector |
| Common/usual name: | Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting |
| Classification Name: | DTL - Cardiovascular 21 CFR 870.4290, Class II |

## D. Predicate Device(s)

| | |
|---|---|
| Trade Name: | GateWay™ Plus |
| Common/usual name: | Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting |
| Classification Name: | DTL - Cardiovascular21 CFR 870.4290, Class II |
| Premarket Notification: | Boston Scientific Corporation previously Scimed Life Systems, Inc. Scimed Gateway Plus, K951089 |

## E. Device Description

The Flush Connector consists of a main lumen body with a hemostasis valve at one end and a rotating male luer at the other end. In addition, the body has a side arm lumen with attached extension tube and female luer fitting. The haemostatic valve is designed to seal around a guide wire, stiffening wire, or other devices; and the side arm tubing is provided for fluid administration and flushing. The rotating male luer is designed to connect to a female luer such as on a catheter. The proposed Flush Connector may be provided as a stand alone device or may be provided in a kit configuration with other legally marketed devices as a convenience to the user.

## F. Intended Use

The Flush Connector is indicated for providing hemostasis around catheters, guidewires, and other devices during general intravascular procedures.

## G. Performance Evaluation

The proposed flush connector was assessed in accordance with various FDA recognized Standards and voluntary industry standards including:. ISO 594-2, EN ISO 11070, EN ISO 8536-9. Testing included evaluation for air and hydrodynamic leak, luer bond flex and pull strength, valve detachment, collar rotation, securement and interface with ancillary devices. ANSI/AAMI/ISO 10993 Cytotoxicity, Sensitization, Intracutaneous Irritation. Acute Systemic Injection, Pyrogenicity, Hemolysis, Complement Activation, and Thromboplastin. ASTM F750, USP 29<88>, USP 31 NF26 <88> and USP (31) <661>; AAMI/ANSI/ISO 10993-7, AAMI/ANSI/ISO 11135-1, AAMI/ANSI/ISO 11138-1, AAMI/ANSI/ISO 11737-1, AAMI ST72, EN 556-1; ANIS/AAMI/ISO 11607 Part 1&2, ASTM F1980, F88, F1929, and F1886.

## H. Substantial Equivalence

Based on responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR - 1 2010

Navilyst Medical Incorporated
c/o Ms. Lorraine Hanley
Director Global Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K091634
Trade/Device Name: Flush Connector
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II (two)
Product Code: DTL
Dated: January 8, 2010
Received: January 11, 2010

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anne R. Zuckerman

for Bram Zuckerman, MD
Division Director,
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number (if Known):** K091634

**Device Name:** Flush Connector

**Indications for Use:**

The Flush Connector is indicated for providing hemostasis around catheters, guidewires, and other devices during general intravascular procedures.

**Prescription Use** ___X___ **AND/OR** **Over-The-Counter Use**_____

**(21 CFR 801 Subpart D)** **(21 CFR 801 Subpart C)**

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Donna R Lichtman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091634